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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,731	07/14/2000	John T. McDevitt	5119-00517	6881

7590

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EXAMINER
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YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/616,731	MCDEVITT ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 413-466, 490-492, 726 and 730 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 413-442, 444-466, 490-492, 726 and 730 is/are rejected.
- 7) ☒ Claim(s) 443 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of claims 413, 415, 424, 432, 433, 443, 460, 465, 490, 491, 726 is acknowledged and has been entered.
2. Claims 413-466, 490-492, 726, 730 are currently pending.

### ***Rejections Withdrawn***

3. Applicant's arguments, see p.12-16, filed January 26, 2005, with respect to the rejection of claims 413-466, 490-492, 726, and 730 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 413-466, 490-492, 726, and 730 under 35 U.S.C. 112, second paragraph, has been withdrawn.
4. Applicant's arguments, see p.12, filed January 26, 2005, with respect to the double patenting rejections have been fully considered and are persuasive. The double patenting rejections has been withdrawn in light of the terminal disclaimer filed.
5. Applicant's arguments, see p. 12, filed January 26, 2005, with respect to the oath have been fully considered and are persuasive. The objection of the oath has been withdrawn.
6. Applicant's arguments, see p.17, filed January 26, 2005, with respect to the rejection of claims 413, 431, 432, 490, and 726 under 35 U.S.C. 102(e) as being anticipated by Wang et al [US 5,922,617] have been fully considered and are persuasive. The rejections of claims 413, 431, 432, 490, and 726 under 35 U.S.C. 102(e) as being anticipated by Wang et al has been withdrawn.

### ***Claim Rejections - 35 USC § 103***

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7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 413-416, 418-430, 433-435, 439, 444, 459-461, 465, 466, 490-492, 726, 730 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfof et al [US 6,485,690].

With respect to claims 413, 444, 490, 726, Pfof et al teach a multiple fluid sample processor comprising a multi-layered fluidic array having microtiter scale reservoirs, connecting microchannels, and sub-microtiter reaction or assay wells (column 2, lines 35-40), where the lower well plate comprises a plurality of wells used to hold reagents, solid supports, particles and/or other materials (column 6, lines 14-21). Pfof et al further teach a vacuum system, such as pump systems (column 6, lines 45-65), which could be utilized to assist in draining and evacuation of excess reagents and wash solvents by applying a vacuum along the lower layer (column 7, lines 15-28). Pfof et al also teach light emitting detection elements arranged in pairs (column 14, lines 53-55) as well as optical elements including LED's, fiber optics, lenses, micro lenses, phase gratings, and other means of detecting the samples (column 11, lines 40-55).

Pfof et al discloses the claimed invention except for the limitation that the vacuum apparatus is at least partially incorporated into the supporting member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to , since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

9. With respect to claims 414-415, Pfof et al teach the lower well plate comprises a plurality of wells used to hold reagents, solid supports, particles and/or other materials (column 6, lines 14-21).

10. With respect to claim 416, Pfof et al teach optical elements including LED's (column 11, lines 40-55).

11. With respect to claims 418, 420, Pfof et al teach that the sensor array is comprised of multiple layers, coupled together tightly to form a liquid tight seal (column 6, lines 22-32).

12. With respect to claims 419, 421, Pfof et al teach that the layers can be made of glass (column 6, lines 33-41), and would therefore be transparent to light.

13. With respect to claim 422, the plates can be made from silicon wafer materials (column 6, lines 33-41), and pretreated with silicon nitride (column 15, lines 10-18, claim 18).

14. With respect to claims 423-425, Pfof et al teach that reagents are added to the openings in the top plate, where they are transferred to the rows and columns. Pressure is then applied to yield the capillary valves and load the reaction wells (column 15, lines 46-67) Once the reactions are completed, the spacer gasket and temperature plate are removed and the reaction wells are evacuated, washed and purged (column 7, lines 45-67, column 8, lines 1-10, figs. 10-18). Pfof et al also teach that the layers can be made of glass (column 6, lines 33-41), and would therefore be transparent to light.

15. With respect to claims 426, Pfof et al teach the lower well plate comprises a plurality of wells used to hold reagents, solid supports, particles and/or other materials (column 6, lines 14-21).

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16. With respect to claims 427-430, 433, the plates or layers may be releasably stacked (column 6, lines 23-24), coupled together tightly to form a liquid tight seal (column 16, lines 36-52), where each of the reaction wells has one or more entrance channels, and one or more exhaust or drain channels, formed in the intersection of two, three or more thin plates which are bonded or fused together (column 6, lines 15-21, figs 8, 9).

17. With respect to claims 434-435, Pfohl et al teach that a layer may contain features created within structures using photolithography (column 14, lines 55-61).

18. With respect to claim 439, Pfohl et al teach fluorescence detection mechanism (column 12, lines 5-17).

19. With respect to claims 459, 460, the limitations recited further limit the analyte, and do not recite what structural limitations would be necessary for the particle to be configured to produce the signal, and therefore have not been given patentable weight.

20. With respect to claims 461, 491, 492, Pfohl et al teach a multiple fluid sample processor comprising a multi-layered fluidic array having microtiter scale reservoirs, connecting microchannels, and sub-microtiter reaction or assay wells (column 2, lines 35-40), where the lower well plate comprises a plurality of wells used to hold reagents, solid supports, particles and/or other materials (column 6, lines 14-21). Pfohl et al further teach that samples can be detected by reaction on the surface of beads (column 11, lines 1-7).

21. With respect to claim 465, 466, Pfohl et al teach a reagent reservoir (column 5, lines 55-60), for filling with a plurality of reagents or other materials (column 2, lines 49-65)

22. With respect to claim 730, Pfohl et al teach the presence of microvalves (column 7, lines 1-5).

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23. Claims 413-433, 437, 439-442, 444-451, 455, 459-461, 465, 466, 490-492, 726, 730 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al [Lavigne et al, Solution-based analysis of multiple analytes by a sensor array: toward the development of an "electronic tongue", June 1998, J Am Chem Soc, 120, 6429-6430] in view of Pfof et al [US 6,485,690].

With respect to claims 413, 444, 490, 726, Lavigne et al teach a sensor array comprising a light source (fig.1), a sensor array with cavities formed within the supporting member (p.6429, col.2), resin beads positioned within the cavities (p.6429, col.2), and a CCD array (p.6429, col.1). Lavigne et al further teaches that the sensor array allows for the simultaneous identification of multiple analytes in solution. Lavigne et al do not teach a vacuum apparatus.

Pfof et al, however, teach that a pressure pumping mechanism or a vacuum pump system may be used to assist in draining and evacuation of excess reagents and wash solvents from the channels and wells of a system (column 6, lines 47-55).

Pfof et al discloses the claimed invention except for the limitation that the vacuum apparatus is at least partially incorporated into the supporting member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to , since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Therefore it would have been obvious to have a vacuum system in the sensor array of Lavigne et al, as suggested by Pfof et al, in order to remove excess reagents and wash solvents during identification of analytes in the solution.

24. With respect to claims 414-415, Lavigne et al teach a 3x3 array of beads, where the beads were positioned within micromachined wells formed in Si/SiN wafers (p.6429, col.2). The array is designed to allow for the simultaneous identification of multiple analytes in solution (p.6429, col.1).

25. With respect to claim 416, Pfof et al teach optical elements including LED's (column 11, lines 40-55).

26. With respect to claims 417-418, Lavigne et al teach a cover plate over the Si/SiN wafers with the wells and a CCD array below the wells interfaced with the sensor array (fig. 1, p.6429, col.2), such that a white light source shines through the cover, through the sensor array, and to the CCD array (fig.1).

27. With respect to claim 419, 421, Lavigne et al show that light from the light source passes through the cover plate and the Si/SiN wafer containing the beads held in pits, and to a CCD array, which would indicate that the bottom and top cover layer are substantially transparent to light produced by the light source (fig.1).

28. With respect to claims 420, Pfof et al teach that the sensor array is comprised of multiple layers, coupled together tightly to form a liquid tight seal (column 6, lines 22-32).

29. With respect to claim 422, 437, 440, Lavigne et al teach a CCD array that is interfaced with the sensor array (p.6429, col.2, fig.1C).



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30. With respect to claims 423-425, Pfoet et al teach that reagents are added to the openings in the top plate, where they are transferred to the rows and columns. Pressure is then applied to yield the capillary valves and load the reaction wells (column 15, lines 46-67) Once the reactions are completed, the spacer gasket and temperature plate are removed and the reaction wells are evacuated, washed and purged (column 7, lines 45-67, column 8, lines 1-10, figs. 10-18). Pfoet et al also teach that the layers can be made of glass (column 6, lines 33-41), and would therefore be transparent to light.

31. With respect to claim 426, the cavity is capable of containing the particle (fig. 1B).

32. With respect to claims 427-430, 433, Pfoet et al teach that the plates or layers may be releasably stacked (column 6, lines 23-24), coupled together tightly to form a liquid tight seal (column 16, lines 36-52), where each of the reaction wells has one or more entrance channels, and one or more exhaust or drain channels, formed in the intersection of two, three or more thin plates which are bonded or fused together (column 6, lines 15-21, figs 8, 9).

33. With respect to claim 439, Pfoet et al teach fluorescence detection mechanism (column 12, lines 5-17).

34. With respect to claims 441, 442, 445, 446, the beads taught by Lavigne et al are poly(ethylene glycol)-polystyrene resin beads derivatized with a variety of indicator molecules (p.6429, col.1) and are 130  $\mu\text{m}$  when dry and 250  $\mu\text{m}$  when wet (p.6429, col.2).

35. With respect to claims 431, 432, the cavity taught by Lavigne et al is tapered such that the width of the cavity narrows, such that the width of the cavity at the bottom of the cavity is less than the width of the particle (fig 1B).

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36. With respect to claims 447-449, 455, the sensors taught by Lavigne et al include alizarin complexone for  $\text{Ce}^{3+}$ ,  $\text{Ca}^{2+}$ , and pH, a boronic ester of resorufin-derivatized galactose for simple sugars (carbohydrates), and fluorescein for pH (p.6429, col.2).

37. With respect to claim 450, Lavigne et al teach that fluorescein, alizarin complexone, and *o*-cresolphthalein complex-one were immobilized on a PEG-PS bead via a dicyclohexylcarbodiimide coupling (p.6429, col.2).

38. With respect to claim 451, Lavigne et al teach that the resin bound boronic acid was saturated with a fluorescently tagged sugar, where addition of D-fructose results in a displacement of the tagged sugar (p.6429, col.2).

39. With respect to claims 459, 460, Lavigne et al teach that the limitations recited further limit the analyte, and do not recite what structural limitations would be necessary for the particle to be configured to produce the signal, and therefore have not been given patentable weight.

40. With respect to claim 461, Lavigne et al teach a 3x3 array of beads, where the beads were positioned within micromachined wells formed in Si/SiN wafers (p.6429, col.2). The particles produce a detectable pattern in the presence of an analyte (fig.2, p.6430, col.2)

41. With respect to claim 465, 466, Pfost et al teach a reagent reservoir (column 5, lines 55-60), for filling with a plurality of reagents or other materials (column 2, lines 49-65).

42. With respect to claims 491-492, Lavigne et al teach a 3x3 array of beads, where the beads were positioned within micromachined wells formed in Si/SiN wafers (p.6429, col.2). The array is designed to allow for the simultaneous identification of multiple analytes in solution (p.6429, col.1).

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43. With respect to claim 730, Pfost et al teach the presence of microvalves (column 7, lines 1-5).

44. Claim 436 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al [Lavigne et al, Solution-based analysis of multiple analytes by a sensor array: toward the development of an "electronic tongue", June 1998, J Am Chem Soc, 120, 6429-6430] in view of Pfost et al [US 6,485,690], in light of Bogart et al [US 5,541,057].

45. With respect to claim 436, Lavigne et al teach that the wells are formed in a silicon wafer. Although Lavigne et al do not specifically state that the wells are reflective, Bogart et al teach that a silicon wafer is a polished reflective material, and therefore the wells of Lavigne et al would be reflective.

46. Claim 438 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al [Lavigne et al, Solution-based analysis of multiple analytes by a sensor array: toward the development of an "electronic tongue", June 1998, J Am Chem Soc, 120, 6429-6430] in view of Pfost et al [US 6,485,690], as applied to claim 413 above, and further in view of Walt et al [US 6,023,540].

Lavigne et al teach a sensor array comprising a detector capable of detecting a multitude of wavelengths, as discussed above. Lavigne et al, however, fail to specifically teach an ultraviolet detector.

Walt et al, however, do teach detectors capable of detecting ultraviolet wavelengths, and further teach that this allows for the determination of the concentration of particular analytes of interest using spectral measurement (column 2, lines 22-26).

Therefore, it would have been obvious to utilize an ultraviolet detector, as suggested by Walt et al, in the sensor array of Lavigne et al and Pfof et al, so that the concentration of specific analytes of interest could be determined by spectral measurement.

47. Claim 452-458 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al [Lavigne et al, Solution-based analysis of multiple analytes by a sensor array: toward the development of an "electronic tongue", June 1998, J Am Chem Soc, 120, 6429-6430] in view of Pfof et al [US 6,485,690], as applied to claim 446 above, and further in view of Wang et al [US 5,922,617].

With respect to claims 452-458, Lavigne et al teach PEG-PS resin beads derivatized with a variety of receptors, as discussed above. Lavigne et al do not teach that the receptors are polynucleotides, peptides, enzymes, biopolymers, antibodies or antigens.

Wang et al, however, do teach using receptors such as polynucleotides, peptides, enzymes, biopolymers, antibodies or antigens (column 3, lines 45-60, column 4, line 10-25, column 5, lines 5-30). Wang et al further teach that this allows for a way to investigate interactions between different compounds or types of compounds (column 1, lines 20-25, column 2, lines 5-15).

Therefore, it would have been obvious in the sensor of Lavigne et al to include more receptors such as polynucleotides, peptides, enzymes, biopolymers, antibodies or antigens, as suggested by Wang et al, in order to be able to investigate interactions between different compounds or types of compounds.

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48. Claims 462-464 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lavigne et al [Lavigne et al, Solution-based analysis of multiple analytes by a sensor array: toward the development of an "electronic tongue", June 1998, J Am Chem Soc, 120, 6429-6430] in view of Pfof et al [US 6,485,690], as applied to claim 413 above, and further in view of Fernwood et al [US 4,493,815].

With respect to claims 462-464, Lavigne et al and Pfof et al teach a sensor array as discussed above, but fail to teach the use of a filter.

Fernwood et al, however, teach the use of a microporous membrane placed immediately beneath an upper template (column 3, lines 49-53), and further teaches that the filter allows for the immobilization of biochemical species, and to separate large complexes from uncomplexed species (column 3, lines 15-20, 50-55). This would allow for a variety of biochemical procedures, including identification, isolation, concentration, and purification of various types of species (column 1, lines 23-30).

Therefore it would have been obvious to have included a microporous membrane for use as a filter in the device of Lavigne et al, as suggested by Fernwood, so that a variety of biochemical procedures, such as identification, isolation, concentration, and purification of various types of species could be performed in the sensor array taught by Lavigne et al.

### ***Response to Arguments***

49. Applicant's arguments with respect to claims 413-466, 490-492, 726, and 730 have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

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50. Claim 443 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

51. No claim are allowed.

52. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

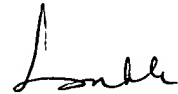
53. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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54. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang  
Patent Examiner  
Art Unit 1641



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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04/15/05